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October 16, 2024

By ECF

Honorable Douglas E. Arpert, U.S.M.J. (Ret.)
Three Gateway Center
100 Mulberry Street, 15th Floor
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**Re: United States ex rel. Silbersher v. Janssen Biotech Inc., et al.,
Civil Action No. 19-12107 (MEF-SDA)**

Dear Judge Arpert:

Defendants Johnson & Johnson (“J&J”), Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC (collectively, “Defendants”) submit this letter in response to Relator’s letter dated October 9, 2024 (“Relator’s Letter”).

Defendants have made 21 witnesses available to Relator for deposition, including corporate representatives on 20 Rule 30(b)(6) topics. The Parties are at an impasse on the scope of Relator’s Topic 13. This topic is excessively broad and unduly burdensome, which prevents Defendants from effectively preparing a witness to address it. This topic is also cumulative of the multiple other topics on which Relator has already received Rule 30(b)(6) testimony, making it unnecessary. Throughout the meet-and-confer process, Relator has failed to articulate with any

reasonable particularity what information he seeks to obtain from this Topic that was not already covered by the others. Defendants therefore respectfully ask the Court to deny Relator's request for Rule 30(b)(6) testimony on Topic 13.

I. Background

As the Court is aware, Relator substantially delayed in pursuing discovery in this case. He waited until the very last day he was permitted to do so to serve a blitz of sweeping, overbroad, and inappropriate written discovery requests. ECF 349 at 2–3. And he waited until just days prior to serve Rule 30(b)(6) notices for testimony on 26 different topics (in addition to the more than 30 fact witness depositions he had demanded). Despite these deficiencies, Defendants agreed to provide Relator with witnesses on a substantial majority of the topics (17 out of 26). The parties disputed other topics, this Court issued an order resolving those disputes, *see* ECF 370, and the Court also directed the Parties to “meet and confer on appropriate limitations to Topic 13,” *id.* at 9.

Relator's Topic 13, as originally served, sought testimony on “[t]he role, Rights, and responsibilities [of each Defendant] relating to the '340 Application, the '440 Application, the '213 Patent, and the '438 Patent.” ECF 349 at 5–6.

Defendants objected to this Topic as excessive, unduly burdensome, and cumulative of Topics 1, 2, and 3. In particular, Defendants argued that the phrase “‘roles, rights, and responsibilities’ is undefined, vague, and ambiguous,” and “prevents Defendants from effectively preparing a witness.” ECF 349 at 4–5. However, Relator refused to narrow the term to “specific issues *relevant to this case.*” *Id.* at 5.

This Court held that the phrase “‘roles, rights, and responsibilities’ is undefined, vague, and ambiguous,” and that Topic 13, as so written, was “expansive, and thus, excessive and unduly

burdensome.” ECF 370 at 9. The Court directed the Parties to limit the scope of Topic 13 such that “(1) the ‘reasonable particularity’ requirement as to Topic 13 is satisfied; and (2) Topic 13 is narrowed so as not to overlap with Topics 1, 2, and 3.” *Id.*

Defendants have met and conferred with Relator at length on this Topic. Throughout, Relator has failed to articulate with reasonable particularity what information he seeks to obtain through this Topic that was not already provided in others.

At one point in the meet-and-confer process, Relator indicated he may be seeking through this Topic information relating to licensing agreements between the Defendants pertaining to the Patents (*i.e.*, the ’213 Patent and the ’438 Patent), or the Patent Applications (*i.e.*, ’340 Application and the ’440 Application).

Defendants then advised Relator that they would provide Rule 30(b)(6) testimony on “intercompany agreements conferring rights or imposing obligations relating” to the Patents or the Patent Applications “to the extent responsive, non-privileged information may have been maintained in the ordinary course of business and is located after a reasonable search.” *See* Ex. B (email between Defendants’ counsel and Relator’s counsel (Sept. 10, 2024)).

Defendants have now completed such a search and determined that no such agreements exist.

Relator, however, continues to insist on a broader scope for Topic 13. As he submitted to the Court, Relator’s current framing of the Topic is as follows:

Intercompany agreements (written or otherwise) concerning each entity’s rights and obligations relating to the ’340 and ’440 applications, and in commercializing or practicing the inventions claimed in the ’213 and ’438 patents.

ECF 379 at 2.

II. Argument

Relator’s current iteration of the topic remains excessively expansive, unduly burdensome,

and cumulative of other Topics on which Rule 30(b)(6) testimony has already been provided.

First, Relator’s attempt to broaden this Topic to include agreements relating to “commercializing or practicing the inventions” claimed in the Patents is a significant and inappropriate expansion.

As noted, Defendants already provided Relator with Rule 30(b)(6) testimony on 20 Topics. Relator limited this Topic, at the outset, to *the Patents and the Patent Applications themselves*. *Supra* at 2. Defendants agreed to provide a corporate representative to testify about any intercompany agreements relating to the Patents and Patent Applications, and have subsequently determined after a reasonable search that no such agreements exist. Now, Relator seeks a broader range of testimony on intercompany agreements “written or otherwise” relating to “*commercializing*” or “*practicing the invention*” covered by the Patents.

That expansion sweeps in a host of issues related to the Zytiga that go well beyond the ambit of Patents and the Patent Applications themselves. Indeed, the terms “commercializing” and “practicing the invention” are undefined, vague, and ambiguous, and conceivably could include a wide range of issues related to Zytiga sales, marketing, licensing, manufacturing, development, and distribution. It would be unreasonably burdensome for Defendants to search for agreements “written or otherwise” related to such a vast number of issues, and virtually impossible to adequately prepare a witness to address them, without Relator focusing this request to the level of reasonable particularity the Rule demands.¹

Second, this Topic, as revised, is cumulative of Rule 30(b)(6) testimony Relator has already

¹ Relator’s request for agreements “written *or otherwise*” is also vague, ambiguous, and unduly burdensome. The term “agreements” necessarily implies written agreements, especially when it is directed to corporate entities such as Defendants, but Relator has not identified with reasonable particularity what other information he is seeking, besides testimony related to written agreements.

received on multiple other topics. As noted, Relator has failed to define the term “commercializing,” which is vague and ambiguous. However, Relator has suggested in prior meet-and-confers that he views the term to include “the marketing and sale of Zytiga.” But new Rule 30(b)(6) testimony on the “marketing” of Zytiga would be cumulative of the three other Rule 30(b)(6) topics on marketing—Topics 22, 23, and 24—on which Defendants already provided corporate testimony in the deposition of Melissa Magee on May 21, 2024. *See* Ex. A at 6–7 (email correspondence between Defendants’ counsel and Relator’s counsel); Ex. C at 26–28 (Defendants’ Responses & Objections to Relator’s 30(b)(6) Topics). Similarly, any Rule 30(b)(6) testimony on “[s]ales of Zytiga” would be duplicative of the five other Rule 30(b)(6) topics—Topics 6, 7, 8, 9, and 10—addressing Zytiga sales on which Defendants already provided corporate testimony on May 30, 2024 (deposition of Ken Nelson). Ex. A at 6–7. Relator had ample testimony to inquire about “commercializing” Zytiga during those depositions, and he offers no reason—and there is none—why he needs yet another Rule 30(b)(6) deposition on these issues.

In addition, Relator’s request for testimony on intercompany agreements “concerning each entity’s rights and obligations” relating to the Patent Applications remains overbroad and cumulative of other topics, for the same reasons identified in the Court’s prior order. Defendants have already provided Relator with Rule 30(b)(6) testimony on at least six topics relating to the prosecution of these Patent Applications:

- Topic 1 addressed Defendants’ “prosecution of all applications leading to the ’438 Patent, including the ’340 and ’440 Applications.”
- Topic 2 addressed Defendants “due diligence relating to the Commercial Success Argument prior to submitting that argument to the Patent Office.”
- Topic 3 addressed “[a]ll facts, issues, and materials that Defendants relied upon or considered in making the Commercial Success Argument.”
- Topic 4 addressed Defendants’ “operating procedures, code of ethics, standards, internal guidance, and requirements for any directors, executives, employees, agents, inventors, and

patent prosecuting attorneys when prosecuting patent applications.”

- Topic 5 addressed “hierarchy, structure, and responsibilities of the relevant legal and patent prosecution departments” for Defendants; and
- Topic 14 addressed the “acquisition, license, or transfer of any Rights related to the ’213 Patent.”²

Relator claims his revision to this Topic is no longer duplicative of these other Topics because none of them expressly employs the phrase “intercompany agreements.” Yet, as their number and breadth plainly demonstrate, intercompany agreements relating to the Patent Applications necessarily fall within many of these topics which include, for example, issues relating to the “prosecution” of the Applications, Defendants’ “hierarchy, structure, and responsibilities” relating to prosecution, and the “acquisition, license, or transfer of rights related to the ’213 Patent.” Relator does not—and cannot—argue that he was denied the opportunity to ask or obtain answers to any questions about intercompany agreements related to the Patent Applications during his depositions on any of these six topics, and he identifies no plausible reason why further Rule 30(b)(6) testimony on these issues is necessary or appropriate.

Finally, although it has no bearing on the scope of Topic 13, it bears emphasis that Relator’s contention that Defendants unreasonably delayed Rule 30(b)(6) depositions in this case lacks foundation. As noted, Relator waited until the 11th hour to serve Rule 30(b)(6) deposition notices, and Defendants worked diligently to provide Relator with witnesses on 17 topics earlier this year. After this Court’s order resolving the Parties’ disputes on other topics, Rule 30(b)(6) depositions remain outstanding on four topics, including Topic 13.

From the start of their meet-and-confer discussions about these remaining topics, both parties expressed a preference to have a single witness provide testimony on all four outstanding

² Andrea Kamage provided Rule 30(b)(6) testimony on Topics 1, 2, and 3 on February 15, 2024; Timothy Tracy provided Rule 30(b)(6) testimony on Topics 4, 5, and 14 on April 11, 2024.

topics, including Topic 13, to the extent practicable and appropriate, for the sake of efficiency. Yet Defendants maintained that the scope of Topic 13 necessarily must be resolved such a deposition could proceed. Defendants advised Relator during the meet-and-confer process that it would not be possible to move forward on the date they had reserved for the final Rule 30(b)(6) deposition if the dispute on Topic 13 were not resolved in advance—either by an agreement between the Parties or by Relator seeking a ruling from this Court. Yet Relator chose not to resolve this matter prior to that date. He failed to come to an agreement with Defendants, despite them meeting and conferring with Relator on this issue on multiple occasions, and he failed to seek the Court’s intervention prior to that date, despite this Court inviting him to do so, if necessary, during the September 18, 2024 status conference.³

³ Relator also asks the Court to order the final Rule 30(b)(6) deposition to commence at “7:30 a.m. ET” on a “mutually convenient date.” This request is unripe, and should be denied in any event. If the Court requires further Rule 30(b)(6) testimony on Topic 13, Defendants will promptly designate a witness, and the parties should meet and confer on deposition logistics at that time.

Relator’s demand arises from the fact that the parties previously discussed Defendants providing Rule 30(b)(6) testimony from a witness employed by Defendants at their facility outside of Brussels, Belgium. Given the location, Defendants offered Relator’s counsel the option to take the deposition in person in Belgium or via videoconference, as an accommodation to Relator’s counsel. Relator’s counsel now seeks the *further* accommodation of taking a video deposition primarily during his own workday, which would require the witness in Brussels to testify substantially into the evening hours. Brussels is six hours ahead of Eastern Time. A seven-hour deposition that begins at 7:30am ET would not begin until 1:30pm Brussels time and likely not conclude until after 10:30pm Brussels time. (The Parties’ experience in this case indicates that a seven-hour deposition takes at least nine hours of “real time” to complete.) Requiring the witness to testify that late into the evening is unreasonably burdensome for the witness. Defendants respectfully submit that the convenience of the witness takes primacy over the convenience of counsel (on both sides), and that depositions should be conducted during a witness’s workday, to the maximum extent reasonably possible.

In any event, this is not a matter that requires the Court’s intervention—at least until Defendants have designated a witness for this Topic 13 and the parties have met and conferred on logistics. This is especially so because Relator’s October 15, 2024 letter to the Court (ECF 383), indicates that he is withdrawing his request for one of the outstanding deposition topics, which suggests a full seven hours may no longer be required for this deposition.

* * *

Based on the foregoing, Defendants respectfully ask the Court to deny Relator's request for further Rule 30(b)(6) testimony on Topic 13.

October 16, 2024

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